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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/038,263

10/24/2001

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EXAMINER

ALEXANDER, LYLE

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/038,263	Applicant(s) XU, TOM C.	
	Examiner Lyle A. Alexander	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 27 February 2008.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 105-121 is/are pending in the application.

4a) Of the above claim(s) 118-121 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) 105-117 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/3/08

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 105-117, drawn to an optical fiber or micro tube terminating with a circular reagent pad, classified in class 422, subclass 82.05.
- II. Claims 118-121, drawn to a ball point shaped device for testing glucose, classified in class 422, subclass 61.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination I has separate utility such as a device for the detection of an analyte other than glucose, such as HCG. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election

shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Newly submitted claims 118-121 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: See the above restriction requirement.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 118-121 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 105-117 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 105 and 112 are not clear if the first, second or both ends have the first diameter. For the purposes of examination it will be assumed both ends have the first diameter.

Claims 106-111 contain a reoccurring typographical error in line 1 referencing "claim 0." For the purposes of examination it will be assumed --claim 105-- was intended.

Claim 107 claims the first and second ends are polished. It is not clear what structural limitations are intended. In the absence of claiming a physical characteristic related to the degree of polishing, the Office will interpret these limitations as the first and second ends are smooth enough to interface with a photometrical device and be affixed to a test pad.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 105-108, 110-114 and 116-117 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Raskas (USP 6,157,442).

Raskas teach in their abstract a sensor device for measuring the concentration of a biological analyte with an optical fiber having a first end in contact with an optical analyzer and a second end in contact with a tip portion. The Office has read the claimed "*optical fiber*" on the taught "**optical fiber**", the claimed "*first end*" on the taught "**first end**", the claimed "*second end*" on the taught "**second end**" and the claimed "*reagent pad*" on the taught "**tip portion**."

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 105-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura (USP 5,859,937).

Nomura teaches an optical fiber sensing device having a first end in communication with optical analyzer and a second end that is textured where reagent is deposited. The Office has read the claimed "*optical fiber*" on the taught "**optical fiber**"

, the claimed “*first end*” on the taught “**first end**” and the claimed “*second end*” on the taught “**textured site upon which reagent is deposited.**”

Normura is silent to the claimed reagent pad that is affixed or bonded to the second end of the optical fiber. The Office has read Normura as teach the reagents are integral with the optical fiber as opposed to the claimed structure of being part of a pad which is attached to the fiber.

In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) the court affirmed the rejection holding, among other reasons, “that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice.”) It would have been desirable to incorporate the reagents into a pad and attach the pad the optical fiber so that one source of optical fibers could be used and different pad attached specific for the analyte of interest. This two piece construction would further be desirable in the form of a kit where one optical fiber could be supplied and a plurality of pads specific for a plurality of analytes. It would have been desirable to modify Normura and place the reagents upon a pad and affix the pad to the end of the optical fiber as “obvious engineering design choice” and to gain the above advantages.

Normura is silent to the surface upon which the sample is applied as being “hydrophilic.”

The court decided In re Boesch (205 USPQ 215) that optimization of a result variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The surface properties, such as hydrophilic or

hydrophobic, are result effective variables with the well known and expected results of attracting or repelling aqueous materials. It would have been desirable when collecting a blood sample to make the collection hydrophilic to gain the advantages of permitting the sample to quickly spread and adhere to the surface. It would have been within the skill of the art to modify Raskas or Nomura and make the sample collecting surface hydrophilic to gain the above advantages and as optimization of a result effective variable.

Claims 109 and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raskas.

See Raskas *supra*.

Raskas is silent to the surface upon which the sample is applied as being "hydrophilic."

The court decided In re Boesch (205 USPQ 215) that optimization of a result variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The surface properties, such as hydrophilic or hydrophobic, are result effective variables with the well known and expected results of attracting or repelling aqueous materials. It would have been desirable when collecting a blood sample to make the collection hydrophilic to gain the advantages of permitting the sample to quickly spread and adhere to the surface. It would have been within the skill of the art to modify Raskas and make the sample collecting surface hydrophilic to gain the above advantages and as optimization of a result effective variable.

Claims 112-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curry in view of Pugh.

See the appropriate paragraph of the 12/1/03 Office action.

In light of the above 35 USC 112 rejections these claims are best understood as having a reagent pad attached to the end of a hollow tube or cone that is in communication with a means for optical analysis. The Office maintains the combination of Curry in view of Pugh teaches all of these elements and have been properly read on the instant claims.

Curry in view of Pugh is silent to the surface upon which the sample is applied as being "hydrophilic."

The court decided In re Boesch (205 USPQ 215) that optimization of a result variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The surface properties, such as hydrophilic or hydrophobic, are result effective variables with the well known and expected results of attracting or repelling aqueous materials. It would have been desirable when collecting a blood sample to make the collection hydrophilic to gain the advantages of permitting the sample to quickly spread and adhere to the surface. It would have been within the skill of the art to further modify Curry and make the sample collecting surface hydrophilic to gain the above advantages and as optimization of a result effective variable.

Response to Arguments

Applicant's arguments filed 2/27/08 have been fully considered but they are not persuasive.

Applicant's remarks were convincing concerning claims 105-111 were convincing with respect to the rejections of Curry in view of Pugh.

Applicant's argued Curry in view of Pugh does not meet claim 112-117.

The Office maintains Curry teach an optical fiber probe for the analysis of a biological analyte this is indistinguishable from that claimed. Pugh teaches a reagent pad placed on a cone or tube spaced from the optical analyzer. The Office maintains there is sufficient motivation to make the combination and this combination meets all of the requirements of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
Art Unit 1797

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